

**Flu Advisory Board (FAB) Meeting  
February 21, 2007  
12:30 p.m. – 2:00 p.m. (EST)**

**Welcome/List Attendees**

**Members in Attendance:**

Cassandra Dowling (MI Hospital Association - MHA); Sharon Maddox (MI Department of Community Health - MDCH); Rosemary Franklin (MDCH); Terri Adams (MDCH); Sue Schryber (Ottawa Co. HD); Pat Krehn (Muskegon Co. HD); Donna Nussdorfer (Washtenaw Co. HD); Susan Bass (IHA of Ann Arbor); Glory Aiken (Wyeth Vaccines); Carol Legwand (Children's Hospital of MI – CHM & Detroit Medical Center - DMC); Janice Arsenault (Wayne Co. Dept. PH); Patricia White (Oakland Co. HD); Carol Bird; Larry S. Anderson (Michigan Association of Ambulance Services); Mark Mlynarczyk (MedImmune); Jon Steketee (MedImmune); Lori Bologna (Sanofi Pasteur); Bill Hagan (Sanofi Pasteur); Bill Spurlock (Sanofi Pasteur); Carolee Besteman (Michigan Primary Care Association); Liz Harton (MDCH/CDC); Teri Lee Dyke (MDCH/MI Society for Infection Control); Susan Vagasky (MDCH); Rachel Potter (MDCH); Kathy Webster (MNA); JoAnne Eakins (Ionia Co. HD); Patricia Simmons?? (Lapeer Co. HD); Pat Vranesich (MDCH); Courtney McFeters (MDCH); Robert Swanson (MDCH)

**Members on the Phone:**

Jane Naasko (Bureau of Licensing; MDCH); Diane McCagg (AIM); Howard Weinblatt (MI State Medical Society); Jill Higgins (MI Osteopathic Association); Jose Guzman (Chiron Vaccines); Stacey Wright (Maxim Health Systems); Becky Blake (Michigan State Medical Society); Tara Green (Kroger); Penrose (sp??); Michael Toscani (Roche); Lisa Neuffer (MI Osteopathic Association); Mary Morris (VNA Western MI)

## **Review of Minutes**

*Liz Harton*

- We changed the agenda a bit; will be hearing subcommittee updates & manufacturers have updates for us as well
- Roche – State of Michigan has purchased over the HHS recommended subsidized max for Oseltamivir (Tamiflu®) (neuraminidase inhibitor)
- 80/20 split between Tamiflu® and Zanamivir (Relenza®)

## **Manufacturers/Shipping Updates/Other Updates as Requested**

**Roche** – no representative present

**GlaxoSmithKline (GSK)** – no representative present

### **Novartis Vaccine (formerly Chiron)**

*Update from Jose Guzman*

- Waiting for CDC to announce the strains of virus for next season
- Currently growing some strains right now and waiting for CDC to indicate which strains will be used for the next flu season
- Wisconsin, Malaysia, Solomon Islands (announced by WHO for 2007-2008 season)
- Will announce February 27<sup>th</sup>
- Waiting to start growing and head to distributors

### **Sanofi Pasteur, Inc.**

- We just closed our RSVP/early reservation opportunity
- 5 week window
- Opportunity to reserve 7 lots of doses
- Could call anytime they wanted; that period has ended
- Results: reserved more than half of projected reserved vaccine
- Today forward (similar to last year) you can go to [www.vaccineshop.com](http://www.vaccineshop.com) to reserve doses or call 1-800 vaccine number
- Reservation went smoothly
- NIC – invitations for Tuesday, March 6<sup>th</sup> - influenza strategy dinner invitation; nice dinner and transportation; CNE as well

### **MedImmune Vaccines, Inc.**

- We have not announced the ordering process yet but that will be coming out shortly and we will communicate that to you
- We have asked them?? to come in and talk about the CAIV and flu mist during the National Program Managers call; very interesting and new information

**MedImmune Vaccines, Inc.**

*Liz Harton* - Dr. MacDonald is here with us to talk about FluMist. Could we have a copy your slides?

*Dr. MacDonald* - Three topics to discuss today:

1. Current strategy for controlling influenza (strengths & weaknesses);
  2. LAIV – efficacy; recently this week – live trial between LAIV and TIV; safety concerns, especially with asthma patients
  3. Duration of protection; when to start dosing; how long protection lasts; implications for compliance; children under the age of 9
- I am sure you are all familiar with this pyramid – 50 to 60 million infections; huge expense to the system; average of 250,000 hospitals per year; 36,000 deaths per year which can double in nasty flu season; last bad season was 2003-2004 and over 153 children died of influenza that year
  - We think of the flu as disease of young children, however that season ('03-'04) of the children who died: 1/3 were age 5 and over; 1/3 were considered high risk; almost ½ were previously healthy which is a scary thought
  - Fully immunized children have some protection against flu; partially vaccinated children really don't have any protection at all
  - Immunization rates at the moment (see slides); as you can see we do a really horrible job of immunizing health care workers and many children
  - Inactive vaccines has been around since 1960s; 70-90 percent efficacy; limited efficacy in the elderly and high risk populations; limited efficacy against drifted strains (when the vaccine and circulating viruses do not match each other); supply problems in the past; need to be administered quite early to provide protection throughout the season
  - Let's look at how vaccines have changed the past few years (see slides)
  - Question we must ask is why bother making LAIV when we have TIV that works?
  - Generally LAIV have longer duration of protection than killed vaccines; higher efficacy as a group; current other vaccines used have excellent track record; using the ENTIRE influenza virus whereas with injected, the only component you are giving is hemagglutinin protein; immune response to LAIV is more similar to the natural response that would occur
  - Works in a different way – spray in nose; antibodies forming in the nasal cavities; antibodies forming in the bloodstream; it serves as a guardian at the gate where flu usually enters the body
  - There have been several head-to-head trials conducted

### *Question & Answer Session for Dr. MacDonald*

- Question: Will it still be called Flumist?
- Answer: Yes, publicly it will still be called Flumist; CAIV-T will be the refrigerated Flumist and LAIV will be the regular Flumist
- Comment: The name was a hot issue before you [Dr. MacDonald] came; we are just wondering if LAIV will still be the accepted generic name for forms, codes, etc.
- Answer: Yes, we can still use these terms as those are still the approved generic names for Flumist
  
- Dr. MacDonald gave an explanation of several studies (see slides); 2<sup>nd</sup> study – recurrent respiratory issues in children; 3<sup>rd</sup> study – all children had mild to bad asthma
- In summary, CAIV-T (new Flumist) had higher relative efficacy against matched and mismatched strains compared with injectable vaccine in children aged 6 to 59 months
  
- Question: The study also looked at one dose protection and what happens when kids get only one dose. This is not a good practice, but it does happen and how well does it fare? There are a lot of children who should be getting two doses who are not
- Answer: The numbers speak for themselves; it is not good when children only get one dose; if you are only going to get one dose, need to make a good decision about what vaccine you are going to get
  
- Providers can dose as early as August and certainly in September and still have protection throughout the flu season.
- Flumist began shipping July 25<sup>th</sup> of this year [2006]
- We are urging physicians to give flu shots to children and adolescents when they are in for their sports physicals, which occurs in late summer or early fall
  
- Question (*Carolee Bateman*) - Some of the reasons we hear TIV comes so late is because it takes so long to make it. What is different here?
- Answer (*Dr. MacDonald*) - 1<sup>st</sup> – we are a small company; we create much less doses; 2<sup>nd</sup> – the number of doses of Flumist made out of one egg is much higher than doses of injectable vaccine that can be made out of that one egg
- We are researching a cell punctured technique over the next couple of years which should help us bring the product to market considerably sooner
  
- Question (*Liz Harton*) - they all have some form of study on cell punctured (??) techniques; this year can we expect an august delivery date?
- Answer (*Mark Mlynarczyk*) - Yes that is true. Expiration would be four or five months and providers need to be careful that they are not using expired vaccines. Our hope is to start getting vaccines out earlier so that you can deliver during school physicals
  
- Question (*Donna Nussdorfer*): What is the age range?

- Answer: 5-49 years, healthy, not pregnant; we would not give this to anyone under the age of 1 year; definitely not give to those with asthma; we will hear about that March 28<sup>th</sup>
- ACIP – briefing book; MedImmune presenting safety to children above 12 months of age; they will be presenting today [February 21, 2007]
- Question: Studies now are focusing on moving the age down. Is there any plan to look at ages over 49?
- Answer (*Dr. MacDonald*) - Yes, we are looking at this. The initial trials did not have enough people to prove efficacy. The trials proved safety in ages 49+, but not efficacy, so MedImmune did not try to get licensure. They are planning to do that now, but the attack rate of flu is relatively low in this age group compared to the attack rate in children. In ages 50+ the flu rate is 6 to 8 percent, therefore we would need to do HUGE trials (20 to 40 thousand people) in this group to see the difference; these are huge and very expensive studies.
- Question (*Carol Legwand*) – Is Flumist only fridge stable? They are shipped with the temperature maintained, but now we have so much room in our large freezers; is it possible that it can be kept in the freezer?
- Answer (*Dr. MacDonald*) – No, if it becomes frozen, it needs to be discarded; Flumist cannot be put in the freezer and it is going to be shipped refrigerated.
- Comment (*Pat Vranesich*) – We were given different information from Nick. Nick said that it was cheaper to transport frozen, therefore it would be shipped frozen and then stored in fridge.
- Answer (*Mark Mlynarczyk*) - We will need to clarify for sure.
- Comment (*Teri Adams*) – The information from CDC says that it will be frozen when shipped and then refrigerated. That is an accident waiting to happen because when something arrives frozen, that is a cue to providers that it should be stored frozen.
- Comment (*Pat Vranesich*) – Yes, there are huge issues with this.
- Answer (*Mark Mlynarczyk*) - If there are any changes in shipping, we will make sure to get some clarification and send to Liz, who will disseminate and send out.
- Question (*Pat Vranesich*) – We are receiving lots of questions about rotavirus. If kids have junky noses, are you still supposed to spray Flumist in there?
- Answer (*Dr. MacDonald*) – It is recommended that if a child has a really congested nose you can wait and even if they sneeze right after administering Flumist, they still have enough in their system for the job to get done.

## **Subcommittee Updates**

*Liz Harton*

- Minutes were sent out yesterday. Before we move onto subcommittee updates, we have two things to discuss.
- **(1) How can we figure out how to bring people together regionally and work together as a community?**
  - We need to ensure we are not over- or under-ordering; we have been getting too much vaccine in some places and not others
  - One place to start is to call Kroger, Maxim, VNAs, etc. and ask how many flu doses were administered; look at where there were pockets of low immunization and gaps; discuss how to proceed for next flu season;
  - We realize there are a lot of issues with asking this information and that people are not going to want to say how many doses were given and ordered;
  - We are hoping to look at this year's data and work together as a community;
  - Liz Harton - Tara or Stacy, do you think this is something we could look at doing again this year?
  - Stacy - Yes it is
  - Tara – Not a problem
  - Pat Vranesich – not all of the VNAs responded but we sent it to those we knew were mass vaccinators; one of the VNAs in the counties responded; Stacy, we can only figure this out by zip code, right?
  - Stacy – correct
  - Liz – LHD, was this info helpful?
  - Liz - Barb Wolicki said that Kalamazoo has a good immunization program; we could use as model or standard for best practices
  - Kathy Webster – This is not a very good year to look at this information, because there has not been much flu activity, therefore most of us have tons of vaccines left over.
  - Liz Harton – That's true. We are going to talk later about how much there will be sitting out there.
  - Pat Vranesich – We were surprised at certain areas that there was more uptake, such as county health departments. Would like to find out who is responding to mass vaccination clinics; even people from out of state were included in the list; whoever happened to want the flu vaccine that day
- **(2) How can we attempt as a group to culminate a statewide campaign that would target mass vaccination clinics in late October and early November? Any comments?**
  - Larry Anderson – I am new to this, but several hospitals and organizations (Bronson, Battle Creek Health System, ambulatory services, etc.) are going to make the flu vaccine mandatory this year. This will significantly add to the demand. 10 to 20 percent were vaccinated before; now up to 65 percent of employees were vaccinated this season and that is without it being mandated yet; this is the first point of patient contact.
  - Pat Vranesich – We are excited to have you on board to share your experiences

- Teri Lee Dyke – Starting in 2007, they have to offer the flu vaccine to health care workers. From now to March it is mandated that these facilities HAVE to offer the vaccine.
- Larry Anderson - One reason that Bronson started this was because adult infectious disease specialists revealed a high percentage of physicians who were not getting the flu vaccine and killing their patients. This will be mandatory, in that HCW will not be on staff if they don't get the vaccine. Staff at Bronson asked themselves, "Why are we doing this?" and decided to just make it mandatory, as no one could say why they weren't currently vaccinating all staff members, so it spread like a flame; Bronson will be featured in a newsletter to share what their strategies were
- Teri Lee Dyke – There have been questions regarding JCAHO and if this will be free of charge or with a cost. Right now, they don't know, but have likened it to getting the Hepatitis B vaccine. I believe that it this free of charge but am not sure.

### **Education & Communication Subcommittee**

#### *Mass Flu Vaccine Training Clinics*

*Pat Vranesich*

- We were thinking of holding a mass flu vaccination clinic using the Minnesota model. Minnesota partnered with mass vaccinators to provide training.
- As so many people attend mass vaccination clinics, we need to get people familiar with state practices and state committees.
- With FAB and MDCH, what would you think of a mass flu vaccination clinic training?
- We could invite Kroger, Maxim, etc. even though many of them are out of state. Additionally, we could invite the MI Society of Pharmacists.
- This would be offered as a one day training
- Minnesota offered this training and was surprised with the response; they gave a certificate to validate that these people attended a training in Minnesota
- This training comforted the public that Kroger and other similar sponsors of flu vaccination clinics, were knowledgeable in this area
- There are concerns about pregnant women and people at high risk being turned away by pharmacists
- This clinic would help us with message development
- We could discuss dates and deadlines, as well as introduce the MCIR registry
- Overall, this would be a way to improve communication with mass vaccinators; what do you think??
- Answer - Great idea; received a couple calls from senior citizens this year who weren't sure if they should go to pharmacies and grocery stores to get their flu vaccine; they had never heard of this before and didn't know if this was legal; helpful in comforting the public
- Question - Where would these trainings be offered? We could use them as "train the trainer" seminars throughout the state in order to really hit different areas
- *Pat Vranesich* - Anyone on the committee that would like to volunteer for this?
- Answer (*Sue Schryber; Pat Krehn; Tara and Stacy on phone interested; Kathy Webster; Janice Arsenault*)



- Comment (*Larry Anderson*) - Another source of manpower would be medics; we could train and be reimbursed by Medicare; in emergency circumstances this would be of assistance
- Also, this will assist us in coordinating messages for seasonal flu; mass clinics will get us talking, collaborating, and forming a partnership

#### *MDCH Influenza Reference Sheet*

*Liz Harton*

- Rachel Potter, Susan Vagasky, and Courtney McFeters have been working on the flu reference sheet which we passed out; so much flu activity is going on at the state level that it is getting lost; so we put this guide together and are passing it out as a draft; please give us comments and feedback; as far as I can see it looks pretty complete to me; any comments?

#### **Long-Term Care Pandemic Survey Results**

*Susan Vagasky*

- Long-term care pandemic survey results
- Concerned with preparedness – level and completeness; stockpiling of medical equipment
- Someone came to Eden last year and was interested in LT care facilities
- Created a quick survey – drawback was that people could exit out at any time and it would still register what they entered at that point; in other words, people had the option to answer what they wanted
- Preparedness is a pretty hot topic this year but the facilities studied had much room for improvement; 26% hadn't even discussed a plan; less than a third were even thinking about absenteeism issues
- We are going to be looking at the data more closely to see how it correlates with the size of the facility
- Overall, long-term care facilities appear to be somewhat concerned about pan flu and some progress is being made; room for improvement and education; staff vaccination rates are low and inconsistent; need for additional education about stockpiling surgical masks; any facility with direct patient care needs to be stockpiling N95s
- Comment – We were asked to speak at Lakeshore long term care in Manistee and found this was such a daunting task for them to even start thinking of everything they would have to do to function on their own; they were overwhelmed by the thought of it; several facilities hadn't even thought about pan flu and their response for failing to do so was that they are waiting to have someone give guidance and get them started; they are scared and don't know where to begin – guidance documents, bureau of health systems who does the licensing could be helpful with this
- Question - Jane are there any requirements for disaster planning for long-term care facilities?
- Answer – They are supposed to look at this in broad perspective and think about what might happen in their area; this is part of our expectations; they need to consider all hazards planning, not just planning for pandemic flu and look at things such as food, equipment, medicine, & day-to-day issues

## Surveillance Update

*Rachel Potter*

- We have not yet peaked in MI; Over-the-counter, drug sales, physicians, etc. are all showing small increases which are incrementally steady over the past four weeks; no state reports of facility outbreaks, no confirmed pediatric deaths, no schools closings due to flu absenteeism
- Currently we are at local activity which is the third highest on five point scale; we have been there for about three weeks
- Seeing small increases across the U.S. in A H1N1 – primary; B Malaysia (Victoria lineage); this strain was in this year's vaccine
- Total of 13 pediatric deaths this season; 13 at this time last year as well
- Next year (2007-2008 season) the only new strain will be the Solomon Islands strain

## Flu Vaccine/Supply & IVEN

*Terri Adams*

- No supply issues; 30,000 in IVEN – not VFC vaccine; no orders we haven't been able to supply
- We can't look at how much providers have, but we can look at LHD; overall there is quite a bit out there
- Pre-booking currently – report March 2<sup>nd</sup> LHD, and we report March 6<sup>th</sup> to CDC; at that time we will know if we can fulfill all of our orders or if we will need to request more
- Comment (*Patricia White*) – we still have VFC providers taking flu vaccine from us; still picking them up and giving out; we put a strong push that they needed to take the vaccines they ordered and if they didn't we encouraged them to use through February and now through March; 40 or 50 doses going out even this week; make sure to encourage second doses
- ACIP will be voting today on the change in recommendations for ages 6 months to 9 years; harmonize with AAP – re-vaccinate if one dose in the previous (first) year and now two doses the second year (voting today); this applies for ages up to 9 years (children who are getting flu vaccine for first time up to 9 years)
- Comment (*Sharon Maddox*) – there is so much private stock left that we have been giving it out for free; we have been trying to just get rid of it and get it in someone's arm; be thinking about that
- Question - Are they increasing the recommendation up to 18 years from 5 years?
- Answer – It is not on the agenda to vote on, but it is being discussed; at the National Influenza Vaccine Summit, they were highly encouraging everyone to go in that direction; ACIP is thinking it might be premature based on evidence and is waiting to let the evidence weigh in on the universal recommendation
- Big call on school-based immunization projects; let CDC know that; assuming they are gathering more data on immunization in school children
- Also looking at pandemic influenza vaccine prioritization; there may be something new on that and will let everyone know within next couple days on that; ACIP is using the whole afternoon today to talk about flu
- We should know the 2007-2008 strains from FDA by February 27<sup>th</sup>
- CAIV - submit Biologic License Application (**BLA**); allows CAIV to be used over 12 months of age without wheezing & doesn't restrict to over age of 5;

- Question – Is this going to happen this year?
- Answer – That would depend on FDA approval and we are expecting ACIP to come out with full 2007-2008 recommendation today; call Greg Wallace at CDC as soon as Terri got the info from VFC; keep a pulse on when orders were going into the manufacturers privately; extend order until we knew what ACIP was going to say?
- CDC - deadline from manufacturing to get their orders in; going to leave it uncapped

### **Flu Gossip**

*Liz Harton*

- Anything to submit to FluBytes - go ahead and e-mail to Courtney
- What does everyone think about extending the FAB meeting another half hour?  
We tend to go over each time.
- Does anyone have any flu gossip? (none)

### **Adjourn**